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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/021,657

12/14/2001

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06/07/2005

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EXAMINER

KUBELIK, ANNE R

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 06/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/021,657	Applicant(s) ALBERTSEN ET AL.	
	Examiner Anne R. Kubelik	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/21/04, 12/21/04, 3/24/05.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5, 8-27, 31, 32 and 34 is/are pending in the application.
4a) Of the above claim(s) 2, 5, 8 and 16-26 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 3, 4, 9-15, 27, 31, 32 and 34 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 14 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 2-5, 8-27, 31-32 and 34 are pending.
2. This application contains claims 2, 5, 8 and 16-26 drawn to inventions nonelected with traverse in the response filed 5 February 2004. The claims also recite sequences other than the elected SEQ ID NO:7, wherein the sequences were non-elected with traverse in the response filed 5 February 2004. A complete reply to the final rejection must include cancellation of nonelected claims and sequences or other appropriate action (37 CFR 1.144). See MPEP § 821.01.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. The rejections of claim 3 under 35 U.S.C. 102(a) as being anticipated by each of Walbot (2000, GenBank Accession Nos:AW519943 and AW424821) and Anderson et al, 2000, GenBank Accession No: BE494080) are withdrawn in light of the 131 Declaration of Tim Fox filed 21 October 2004.

Claim Objections

5. Claims 12-13 and 32 are objected to because of informalities. The objection is different from the objection set forth in the Office action mailed 11 May 2004, as applied to claims 3, 10-15, 28-30 and 32-33.

In claims 12-13 and 32, a comma should be inserted before “wherein”.

Claim Rejections - 35 USC § 112

6. Claims 3-4, 9-15, 27 and 31-32 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 11 May 2004, as applied to claims 1, 3-4, 6-7, 9-15, and 27-33. Applicant's arguments filed 21 October 2004 have been fully considered but they are not persuasive.

Applicant urges that the claims recite a structure and a function (response pg 10).

This is not found persuasive because the necessary and sufficient structural elements associated with the "impacting male fertility" function are not described.

Applicant urges that the written description guidelines indicate that hybridization claims have adequate description; one of skill in the art would not expect much variation in the sequences and the claims recite the functional property of impacting male fertility (response pg 10).

This is not found persuasive because the specification describes no sequences that hybridize to SEQ ID NO:7 and impact male fertility. The guidelines state that a known or disclosed correlation between function and structure is required.

7. Claim 34 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection is repeated for the

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reasons of record as set forth in the Office action mailed 11 May 2004. Applicant's arguments filed 21 October 2004 have been fully considered but they are not persuasive.

Applicant urges that examples 1-6 give ample description of how to isolate the sequence in the deposited seeds (response pg 10-11).

This is not found persuasive because the claim requires that ATCC deposit 98931 be available under the conditions detailed below.

Applicant urges that a statement in support of the deposit has been submitted (response pg 11).

This is not found persuasive because no such statement has been filed.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and,
- (e) the deposit will be replaced if it should ever become inviable.

In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.801 - 1.809 [MPEP 2401-2411.05] for additional explanation of these requirements.

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8. Claims 3-4, 9-15, 27, 31-32 and 34 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 11 May 2004, as applied to claims 1, 3-4, 6-7, 9-15 and 27-34. Applicant's arguments filed 21 October 2004 have been fully considered but they are not persuasive.

Applicant urges that the sequence of the genomic DNA and cDNA is known, as is the expression pattern in tassels, and the cloning steps were taught for this and for another sequence, and hybridization conditions were taught (response pg 11).

This is not found persuasive because the specification does not teach where to find male-sterility DNAs that hybridize to SEQ ID NO:7 under the recited conditions.

Applicant urges that the function is readily assayed because the sequence is one that when mutated causes male sterility (response pg 11-12).

This is not found persuasive because of the problems with antisense suppression and because the specification does not teach how to do other methods of site-specific mutation. The specification does not teach targeted mutagenesis of the SBMu200 gene within maize, much less in any other plant.

Applicant urges that mutating a sequence to stop expression of a gene does not require undue experimentation, citing a reference, and identification of the essential regions in SBMu200 promoter in Example 5 shows how to do so via deletion analysis; thus, it is not necessary to make all possible single amino acid substitutions (response pg 12).

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This is not found persuasive. What Applicant did in Example 5 was attach deletion fragments of the promoter, SEQ ID NO:5, to a reporter and put that into an unidentified plant species to look for the location of reporter expression; the effect that the construct had on endogenous gene expression was not studied, and an effect would not be expected. Thus, Example 5 does not teach how to mutate the sequence to stop expression of SEQ ID NO:7 or any nucleic acid that hybridizes to it. The reference could not be considered because it was not sent.

Applicant urges that antisense expression has been used for many years, and while agreeing with the problems raised in the Office action, states that it is frequently used by those of skill in the art, citing several references (response pg 12-13).

This is not found persuasive. The specification does not teach how to use SEQ ID NO:7 as an antisense suppressor and Applicant agrees that the process is not straightforward. The references could not be considered because they were not sent.

See *Genentech, Inc. v. Novo Nordisk, A/S*, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that disclosure of a “mere germ of an idea does not constitute [an] enabling disclosure”, and that “the specification, not the knowledge of one skilled in the art” must supply the enabling aspects of the invention.

9. Claims 1, 3-4, 6-7, 9-15 and 27-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections. The rejection is repeated for the reasons of record as set forth in the Office action mailed 11 May

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2004, as applied to claims 1, 3-4, 6-7, 9-15 and 27-33. Applicant's arguments filed 21 October 2004 have been fully considered but they are not persuasive.

Claim 3 is indefinite in its recitation of "An isolated DNA molecule ... comprising a nucleotide sequence ... and those sequences which hybridize ...". Does the nucleotide sequence comprise both a nucleic acid of SEQ ID NO:1, 3 or 7 AND a nucleotide sequence that hybridizes to a nucleic acid that encodes SEQ ID NO:1, 3 or 7?

Applicant urges that claim 3 now recites a nucleotide sequence (response pg 14).

This is not found persuasive because it is unclear if Applicant intends to claim a sequence comprising both SEQ ID NO:1, 3 or 7 AND a sequence that hybridizes to one of those. It is noted that if the claim were allowed as stands, Applicant would not be covered for a nucleotide sequence comprising only SEQ ID NO:7, for example.

Claims 3 and 12-13 are indefinite in their recitation of "impacting". It is entirely unclear what one does to impact the gene. It is also unclear how doing anything to the gene, which may not even be in a plant, would affect the fertility of a plant.

Applicant urges that "impacting" means "to have an impact on, citing web pages, and urges the that the specification states that the sequence can turn male fertility off or on (response pg 14).

This is not found persuasive. If Applicant wishes the term to mean that male fertility is turned off or on, then the claim should be so amended. The web pages could be considered because they were not sent.

Claim 13 is indefinite in its recitation of "A method of impacting fertility of a plant comprising impacting a nucleotide sequence in the plant encoding the amino acid sequence of

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any of SEQ ID NOs 2, or 4 the nucleotide sequences of any of SEQ. ID Nos. 1, 3, or 7 and those sequences...”. Does the method comprise “impacting” a) nucleotide sequence encoding SEQ ID NOs 2, or 4 OR b) SEQ. ID Nos. 1, 3, or 7 AND sequences that hybridize?

Applicant urges that the amended to add “or” makes the claim clear (response pg 14).

This is not found persuasive for the reasons indicated for claim 3, above.

Claim 14 lacks antecedent basis for the limitation “the sequence expression”.

Applicant urges that the claim is amended to provide antecedent basis (response pg 15).

This is not found persuasive because there is no antecedent basis for this phrase.

Claim 31 is indefinite because more than one thing cannot be claimed in a claim. “cells” should be made singular and an article should start the claim.

Applicant did not address this rejection.

Claim Rejections - 35 USC § 102

10. Claims 3-4, 9-15, 27 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Albertsen et al (1998, US Patent 5,850,014). The rejection is repeated for the reasons of record as set forth in the Office action mailed 11 May 2004, as applied to claims 1, 3-4, 6-7, 9-15, 27 and 31. Applicant’s arguments filed 21 October 2004 have been fully considered but they are not persuasive.

Applicant urges that there is no basis to believe these sequences would hybridize under the recited conditions (response pg 15).

This is not found persuasive because the high salt concentration of the hybridization conditions make them very low stringency.

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Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

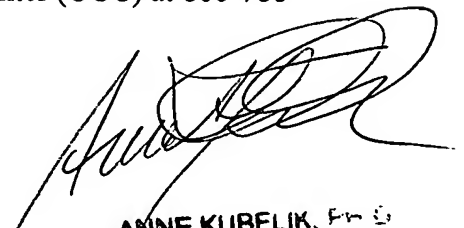
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The central fax number for official correspondence is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Anne R. Kubelik, Ph.D.
May 27, 2005



ANNE KUBELIK, Ph.D.
PRIMARY EXAMINER